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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/776,311	02/11/2004	Anthony J. Kinney	BB1538USNA	4023

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E I DU PONT DE NEMOURS AND COMPANY
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WILMINGTON, DE 19805

EXAMINER

FOX, DAVID T

ART UNIT	PAPER NUMBER
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1638

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/25/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/776,311

Applicant(s)

KINNEY ET AL.

Examiner

David T. Fox

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 September 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 11, 12, 16-18, 21-28 and 140 is/are pending in the application.
- 4a) Of the above claim(s) 21-25 and 140 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 11, 12, 16-18 and 26-28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 September 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>21 September 2006</u> . | 6) <input type="checkbox"/> Other: _____ |

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The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Formal Matters

The Petition under 37 CFR 1.48(b) to change inventorship, filed 21 September 2006, has been GRANTED. Inventors Hitz and Kolar will be deleted.

Replacement Figure 3 submitted 21 September 2006 has been approved, thus obviating the objection to the specification of record.

Restriction/Election

Newly submitted claim 140 is directed to an invention that is independent or distinct from the invention originally claimed for the following reasons:

The claim is drawn to "by-products" of seed processing, which by-products include oil and gums, neither of which contains genetic material, and both of which require seed processing methods and reagents, each not required by elected Group I. Claim 140 corresponds to non-elected Group XI, non-elected without traverse in the Election of 05 May 2006.

Since applicant has received an action on the merits for the originally presented invention, namely Group I encompassing transgenic plants and seeds containing modified genetic material, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim 140 is withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim Objections

Claim 12 is objected to in its recitations of the abbreviations "EPA, DPA and DHA", as it is unclear to what these refer. The claim should be amended to include the full length chemical name of each compound, followed by the abbreviation in parentheses. The full names of EPA and DHA may be found on page 1 of the specification. The full name of DPA may be found on page 10 of the specification. The recitation of the full name of each chemical compound in one claim will obviate the need for a similar recitation in all subsequent claims.

Claim Rejections

All outstanding rejections not repeated below have been obviated by Applicant's amendments and response of 21 September 2006.

Product of Nature

Claims 16-18 remain rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter, as stated on page 3 of the last Office action.

Applicant's arguments filed 21 September 2006 have been fully considered but they are not persuasive. Applicant urges that the amendment to claim 1 has obviated this rejection. Applicant further urges that plants do not naturally produce EPA, DPA or DHA, as demonstrated by Sayanova et al appended to the amendment of 21 September 2006 .

The Examiner maintains that seeds of a transgenic plant encompass untransformed seeds, due to Mendelian segregation of the transgene during the

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crossing process used to produce seed. If the transgene were lost, the seed and progeny plants produced therefrom would not produce oil comprising EPA, DPA or DHA. The following amendments would obviate this rejection:

In claims 16-18, before the period, insert ---, wherein said seeds comprise the transgene---.

All claim amendments should comply with 37 CFR 1.121(c). Note that the above amendment alone would not obviate the outstanding rejections under 35 USC 112, first paragraph.

Enablement

Claims 1, 11-12, 16-18 and 26-28 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for claims limited to soybean plants transformed with particular genes which produce oil having a particular fatty acid profile; does not reasonably provide enablement for claims broadly drawn to any oilseed plant containing any transgene and producing oil exhibiting any fatty acid profile. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims, as stated on pages 4-10 of the last Office action.

Applicant's arguments filed 21 September 2006 have been fully considered but they are not persuasive. Applicant urges that the references cited by the Examiner were either drawn to medium length fatty acids and are thus not applicable to the instant situation, or else confirmed the success of Applicant's method.

The Examiner maintains that the cited references teach the general unpredictability inherent in manipulating fatty acid composition in transgenic plants, and thus are eminently applicable to the instant situation. Furthermore, Applicant admits that plants inherently "lack the metabolic pathway necessary to synthesize a PUFA" (see, e.g., page 7 of the Response of 21 September 2006, fourth full paragraph), thus supporting the Examiner's position that the production of said PUFAs in a variety of plant species containing different endogenous fatty acid metabolism enzymes and substrates is unpredictable.

Furthermore, as admitted by Applicant, Robert et al confirm that soybean is particularly suited to PUFA production due to substrate availability (see, e.g., page 9 of the Response of 21 September 2006, top paragraph), thus supporting the Examiner's position regarding the unpredictability inherent in transforming any other oilseed crop species. As also admitted by Applicant, Robert et al imply that Applicant's success was due to the use of particular transgenes (see, e.g., paragraph bridging pages 8 and 9 of the Response), also supporting the Examiner's position that the use of non-exemplified transgenes is unpredictable.

Applicant also states that Wu et al teach that the use of large numbers of transgenes and "the same method as Kinney et al" resulted in the accumulation of PUFAs in transgenic rapeseed (see, e.g., page 9 of the Response, second full paragraph), further supporting the Examiner's position regarding the requirement for particular transgenes. However, Wu et al appeared to recover oil with low levels of DHA, in contrast to Applicant's results with soybean, thus confirming the Examiner's

position that particular crop species and particular transgenes are required to practice the claimed invention.

Written Description

Claims 1, 11-12, 16-18 and 26-28 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, as stated on pages 10-13 of the last Office action.

Applicant's arguments filed 21 September 2006 have been fully considered but they are not persuasive. Applicant urges that the written description rejection is improper for the same reasons that the enablement rejection was improper, particularly in view of the teachings of Robert et al.

The Examiner maintains that Robert et al confirm that particular transgenes are required for obtaining the claimed invention. Robert et al do not provide additional species of transgenes, other than those utilized by Applicant, to further characterize the claimed genus of any transgene from any source organism and encoding any enzyme or other gene product. Accordingly, the claimed genus remains inadequately described by the few species disclosed in the specification.

Conclusion

The claims remain free of the prior art, as stated on page 13 of the last Office action.

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David T. Fox whose telephone number is 571-272-0795. The examiner can normally be reached on Monday through Friday from 10:30AM to 7:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg, can be reached on 571-272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

January 12, 2007

DAVID T. FOX
PRIMARY EXAMINER
GROUP 180-1638

